ENROLLMENT

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed*: (dy/mth/yr)	Protocol #	Institution:	Patient ID:
Sex (circle): M F	Date of Birth*:		Age:
Registration Date* (dy/mth/yr):		Race Code:	
Body Weight (kg):	Height (cm):		Body Surface Area (m^2):
Patient Subgroup: _____ Reg. Group: _____ Reg. Institution: _____			Country Code: Postal Code: Method of Payment**:
Primary Site:			
Stage of Disease:		CDUS Disease Code:	
Histology/Cytopathology:			
Date of Confirmation of Histology* (dy/mth/yr):			
Date of Diagnosis* (dy/mth/yr):		Performance Status:	
Date Informed Consent Signed*: _____ Informed Consent Version: _____		CDUS Treatment Assignment Code at Enrollment:	

*Use a three-letter abbreviation for month in all dates (e.g. 01/Jan/00)

**Method of Payment Codes

1 = Private Insurance
2 = Medicare
3 = Medicare and Private Insurance
4 = Medicaid
5 = Medicaid and Medicare
6 = Military or Veterans Sponsored NOS
6a = Military Sponsored (including CHAMPUS &TRICARE)
6b = Veterans Sponsored
7 = Self Pay (No Insurance)
8 = No means of payment (no insurance)
98 = Other
99 = Unknown

PRIOR TREATMENT SUMMARY

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution	Patient ID:

Type of Therapy	CDUS Code	Any therapy? [Y]es [N]o [U]nknown	If Yes, Date of Last Dose (dy/mth/yr)
Chemotherapy single agent systemic	23518	Y / N / U	
Chemotherapy multiple agents systemic	23514	Y / N / U	
Chemotherapy (NOS)	900102	Y / N / U	
Hormonal	23557	Y / N / U	
Surgery	4058	Y / N / U	
Immunotherapy	900104	Y / N / U	
Extensive Radiation	900106	Y / N / U	
Limited Radiation	900108	Y / N / U	
Radiation (NOS)	900110	Y / N / U	
Bone Marrow Transplant	3487	Y / N / U	
Gene Therapy	900114	Y / N / U	
Prior Therapy (NOS)	900112	Y / N / U	
Non – Cytotoxic Chemotherapy	800116	Y / N / U	

Details must be provided for the following on the appropriate Supplemental Therapy Case Report Form for the following only as mandated by specific protocols:

1) the last treatment prior to enrollment
2) any prior stem cell toxic therapy (e.g. mitomycin C) or cardiotoxic therapy (e.g. doxorubicin or other anthracycline) if relevant to the study agent.
3) Therapies used to determine “extensive prior therapy” if specified in protocol
4) Any therapies restricted by the protocol eligibility criteria, either specific drugs or number of prior therapy (e.g. no more than two prior chemotherapy regimens for metastatic disease).

Additional details of the supplemental prior therapy Case Report Forms need only be completed when specified by the protocol

PRIOR THERAPY SUPPLEMENT

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

	Date of First Dose (dy/mth/yr) ---------- Date of Last Dose (dy/mth/yr)	Agent ---------- Schedule	Total Dose ---------- Dose Units	Best* Response	CDUS Therapy Type Code**
1.	----------	----------	----------		
2.	----------	----------	----------		
3.	----------	----------	----------		
4.	----------	----------	----------		
5.	----------	----------	----------		
6.	----------	----------	----------		
7.	----------	----------	----------		
8.	----------	----------	----------		

This form is only needed for protocols that specify acquiring details of prior therapy, as noted at the bottom of the PRIOR TREATMENT SUMMARY FORM.

*Code response as CR, PR, MR, SD, PD, AJ, PA, NE, NA, or UK.

**See code on Prior Treatment Summary Form.

PRIOR RADIATION SUPPLEMENT

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

	Radiation Type --- CDUS Therapy Code*	Date First Dose (dy/mth/yr) --- Date Last Dose (dy/mth/yr)	Site --- Schedule	Dose --- Dose Units	Best** Response
1.	---	---	---	---	
2.	---	---	---	---	
3.	---	---	---	---	
4.	---	---	---	---	
5.	---	---	---	---	
6.	---	---	---	---	
7.	---	---	---	---	
8.	---	---	---	---	

Use only if mandated by protocol.

*900108 = Limited Radiation, 900106 = Extensive Radiation, and 900110 = Radiation NOS.
**Code response a CR, PR, MR, SD, PD, AJ, PA, NE, NA or UK.

PRIOR SURGERY SUPPLEMENT

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

	Date (dy/mth/yr)	Procedure/Site* Findings Residual Disease	CDUS Type Code (Circle One)
1.		Procedure/Site: _____ Findings: _____ Residual Disease: _____	Therapeutic (4058) --- Not (-1)
2.		Procedure/Site: _____ Findings: _____ Residual Disease: _____	Therapeutic (4058) --- Not (-1)
3.		Procedure/Site: _____ Findings: _____ Residual Disease: _____	Therapeutic (4058) --- Not (-1)
4.		Procedure/Site: _____ Findings: _____ Residual Disease: _____	Therapeutic (4058) --- Not (-1)
5.		Procedure/Site: _____ Findings: _____ Residual Disease: _____	Therapeutic (4058) --- Not (-1)

Use only if mandated by protocol. *Procedures for study disease, including diagnosis.

CONCOMITANT MEASURES/MEDICATION

NCI/DCTD/CTMS CASE REPORT FORM

(Include all supportive measures instituted while on study)

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

	Start Date (dy/mth/yr) ---------- Stop Date (dy/mth/yr)	Agent Or Procedure	Total Daily Dose ---------- Units	Schedule ---------- Reason
1.	----------		----------	----------
2.	----------		----------	----------
3.	----------		----------	----------
4.	----------		----------	----------
5.	----------		----------	----------
6.	----------		----------	----------
7.	----------		----------	----------
8.	----------		----------	----------
9.	----------		----------	----------
10.	----------		----------	----------

*Use “ongoing” if medication started > 1 month prior to study initiation.

ELIGIBILITY CHECKLIST

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Patient ID:
Checklist #:	Effective Date (dy/mth/yr):		Waiver #:

Eligibility Checklist	Yes	No	N/A	
1.	[ ]	[ ]	[ ]	1.
2.	[ ]	[ ]	[ ]	2.
3.	[ ]	[ ]	[ ]	3.
4.	[ ]	[ ]	[ ]	4.
5.	[ ]	[ ]	[ ]	5.
6.	[ ]	[ ]	[ ]	6.
7.	[ ]	[ ]	[ ]	7.
8.	[ ]	[ ]	[ ]	8.
9.	[ ]	[ ]	[ ]	9.
10.	[ ]	[ ]	[ ]	10.
11.	[ ]	[ ]	[ ]	11.
12.	[ ]	[ ]	[ ]	12.
13.	[ ]	[ ]	[ ]	13.
14.	[ ]	[ ]	[ ]	14.
15.	[ ]	[ ]	[ ]	15.
16.	[ ]	[ ]	[ ]	16.
17.	[ ]	[ ]	[ ]	17.
18.	[ ]	[ ]	[ ]	18.
19.	[ ]	[ ]	[ ]	19.
20.	[ ]	[ ]	[ ]	20.
21.	[ ]	[ ]	[ ]	21.
22.	[ ]	[ ]	[ ]	22.
23.	[ ]	[ ]	[ ]	23.
24.	[ ]	[ ]	[ ]	24.
25.	[ ]	[ ]	[ ]	25.
26.	[ ]	[ ]	[ ]	26.
27.	[ ]	[ ]	[ ]	27.
28.	[ ]	[ ]	[ ]	28.
29.	[ ]	[ ]	[ ]	29.
30.	[ ]	[ ]	[ ]	30.
31.	[ ]	[ ]	[ ]	31.
32.	[ ]	[ ]	[ ]	32.
33.	[ ]	[ ]	[ ]	33.
34.	[ ]	[ ]	[ ]	34.
35.	[ ]	[ ]	[ ]	35.
36.	[ ]	[ ]	[ ]	36.
37.	[ ]	[ ]	[ ]	37.
38.	[ ]	[ ]	[ ]	38.
39.	[ ]	[ ]	[ ]	39.
40.	[ ]	[ ]	[ ]	40.

Eligibility: [ ] Patient satisfies all criteria.

[ ] Patient not formally eligible, but admitted to study because (state reason):

_____

_____

BASELINE MEDICAL HISTORY

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:
Examination Date: (dy/mth/yr)				

Body System	History If Abnormal
H/E/E/N/T	
Neck	
Respiratory	
Cardiovascular	
Gastrointestinal	
Musculoskeletal	
Dermatologic	
Hematopoietic/Lymph	
Endocrine/Metabolic	
Urinary	
Genitalia	
Breasts	
Pelvis	
Abdomen	
Neurologic	
Psychologic	
Other	

BASELINE SYMPTOMS

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

	Onset Date (dy/mth/yr)	Symptom Description ---------- CDUS Toxicity Type Code	Grade*	Related To Disease? [Y]es [N]o [U]nknown
1.		----------		
2.		----------		
3.		----------		
4.		----------		
5.		----------		
6.		----------		
7.		----------		
8.		----------		

*Grade: 1 = Mild, 2 = Moderate, 3 = Severe, and 4 = Life-threatening

EXTENT OF DISEASE

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

			Lesion #	Lesion #	Lesion #	Lesion #	Lesion #
Organ							
Description of Lesion							
Previously Irradiated (Y/N)							
Measurable/Non-Measurable (M/N)							
Followed For Response (Y/N)							
____ / ____ / ____ dy / mth / yr	How Measured						
	Measurement						
	*Eval Number	**Eval Code					
____ / ____ / ____ dy / mth / yr	How Measured						
	Measurement						
	*Eval Number	**Eval Code					
____ / ____ / ____ dy / mth / yr	How Measured						
	Measurement						
	*Eval Number	**Eval Code					
____ / ____ / ____ dy / mth / yr	How Measured						
	Measurement						
	*Eval Number	**Eval Code					

* Evaluation Number: Number each evaluation sequentially, 0 = Baseline, 1 = First evaluation, 2 = Second evaluation, etc.

** Evaluation Code: Enter N for any New Lesion
For Non-measured disease Only, enter R = Resolved, D = Decreasing, I = Increasing, S = Stable

PHYSICAL EXAM

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

Examination Date* (dy/mth/yr):

Body System	Normal (N) Abnormal (A) Not Examined (X)	Comment If Any Change From Baseline
H/E/E/N/T		
Neck		
Respiratory		
Cardiovascular		
Gastrointestinal		
Musculoskeletal		
Dermatologic		
Hematopoietic/Lymph		
Endocrine/Metabolic		
Urinary		
Genitalia		
Breasts		
Pelvis		
Abdomen		
Neurologic		
Psychologic		
Other		

*Baseline and follow-up

STUDY DRUG ADMINISTRATION

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

Start Date (dy/mth/yr) / Time hr:min	Course #	Drug ------------------- Lot #	Dose Level and Units --------------------------------- Actual Dose and Units		Schedule ------------------- Route	Duration -------------- Units
Date		-------------------	Dose Level	Units		
Time			Actual Dose	Units		
Date		-------------------	Dose Level	Units		
Time			Actual Dose	Units		
Date		-------------------	Dose Level	Units		
Time			Actual Dose	Units		
Date		-------------------	Dose Level	Units		
Time			Actual Dose	Units		
Date		-------------------	Dose Level	Units		
Time			Actual Dose	Units		
Date		-------------------	Dose Level	Units		
Time			Actual Dose	Units		
Date		-------------------	Dose Level	Units		
Time			Actual Dose	Units		
Date		-------------------	Dose Level	Units		
Time			Actual Dose	Units		
Date		-------------------	Dose Level	Units		
Time			Actual Dose	Units		
Date		-------------------	Dose Level	Units		
Time			Actual Dose	Units		

COURSE INITIATION

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #	Institution:	Patient ID:
Course #: _____		Start Date of Course: (dy/mth/yr) _____	
Arm: _____		CDUS Treatment Assignment Code: _____	
Weight: _____ kg	Height: _____ cm	Body Surface Area: _____ m^2	
CDUS Treating Institution: _____			

COURSE ASSESSMENT

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #	Institution:	Patient ID:

Start Date of Course (dy/mth/yr): _____

Was dose change done from previous course? (other than due to weight changes)
[ ] (0) NA, this is First Course
[ ] (1) Yes, Planned
[ ] (2) Yes, Unplanned
[ ] (3) No
[ ] (9) Unknown

If YES, explain in Comments Case Report Form with note type CA

Course Disposition: [ ] Completed

[ ] Discontinued

Response Assessment:

NA [ ] Not Assessed (reason): _____

CR [ ] Complete Response

PR [ ] Partial Response

MR [ ] Less than Partial response

SD [ ] Stable Disease

PD [ ] Progressive Disease

NE [ ] Not Evauable (reason): _____

NP [ ] Not Applicable per protocol

Date Onset of Response: _____
(CR, PR, MR, SD, or other assessment checked above)

Date Onset of Progression: _____

Any Toxicity: [ ] Yes [ ] No

ADVERSE EVENTS

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #	Institution:	Sheet #	Patient ID:

Start Date of Course: (dy/mth/yr) Adverse Event Description --- CDUS Toxicity Type Code	Onset Date (dy/mth/yr) --- Resolved Date (dy/mth/yr)	AER Filed (Y/N/U)	Grade*	Attribution**	Dose Limiting Toxicity (Y/N)	Serious	Action	Therapy	Outcome
----------	----------								
----------	----------								
----------	----------								
----------	----------								
----------	----------								
----------	----------								
----------	----------								
----------	----------								
----------	----------								

*Refer to NCI Common Toxicity Grading Criteria.

**Please provide a comment on the Comment Case report Form about the likely attribution of the adverse event, if not definitely attributable to the study drug.

Grade	Attribution	Serious	Action	Therapy	Outcome
1 = Mild	1 = Unrelated	1 = No	1 = None	1 = None	1 = Recovered
2 = Moderate	2 = Unlikely	2 = Life-threatening	2 = Dose reduced	2 = Symptomatic	2 = Still under treatment/ observation
3 = Severe	3 = Possible	3 = Death	3 = Regimen interrupted	3 = Supportive	3 = Alive with sequelae
4 = Life-threatening	4 = Probable	4 = Disability	4 = Therapy discontinued	4 = Vigorous supportive	4 = Died
5 = Fatal	5 = Definite	5 = Hospitalized	5 = Interrupted/reduced		
		6 = Congenital anomaly			
		7 = Jeopardizes patient / requires intervention			

COMMENTS

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

	Date All notes (dy/mth/yr)	Type*	Notes and Remarks
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			
16.			
17.			
18.			
19.			
20.			
21.			
22.			
23.			
24.			
25.			

* The following type-codes may be used to link notes to the relevant form, TX = Adverse Events, XT = Extent of disease, MH = Baseline Medical History. For any other sheet to be linked use the two letter identifier given at the bottom of each panel (e.g., PH is used at the bottom of this sheet, so PH is the identifier).

OFF STUDY SUMMARY

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: dy/mth/yr)	Protocol #	Institution:	Patient ID:

Date Off Study: (dy/mth/yr) _____

Reason for off study:

[ ] C Study Complete
[ ] L Lost to Follow-up
[ ] R Refused Further Treatment
[ ] T Toxicity
[ ] P Disease Progression
[ ] V Protocol Violation
[ ] N Not Treated
[ ] A Alternative Treatment
[ ] I Ineligible
[ ] S Complicating Disease
[ ] D Death On Study
[ ] O Other (explain)

_____

_____

Best Response to Treatment:

[ ] CR Complete Response
[ ] PR Partial Response
[ ] MR Less than Partial Response
[ ] SD Stable Disease
[ ] PD Progression
[ ] NE Not Evaluable
[ ] NA Not Assessed

Date Onset of Best Response: (dy/mth/yr) _____
(only CR, PR, MR, SD or other assessment checked above, except PD)

Date of Relapse: (dy/mth/yr) _____
(e.g. if NED or Adjuvant)

Date of Progression: (dy/mth/yr) _____

FOLLOW-UP

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #	Institution:	Patient ID:

Survival

Date of Last Contact:: (dy/mth/yr) _____

Date of Death: (dy/mth/yr) _____

[ ] 5 Died
[ ] 1 Alive with disease
[ ] 2 Alive with no evidence of disease
[ ] 3 Alive disease status unknown
[ ] 4 Unknown (explain)_____

Cause of Death:

[ ] M Malignant Disease
[ ] T Toxicity from Protocol Treatment
[ ] I Infection
[ ] O Other (explain) _____

Autopsy: Yes [ ] No [ ] Unknown [ ]

Cause of Death at Autopsy:

[ ] M Malignant Disease
[ ] T Toxicity from Protocol Treatment
[ ] I Infection
[ ] O Other (explain)_____

Sites of Disease at Autopsy:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____

INFECTION EPISODE

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

Onset Date (dy/mth/yr) Resolved Date (dy/mth/yr)	Infection Type: ____________________ Primary Site: ____________________ Infectious Agent: ____________________	Treatments: ____________________ ____________________ Outcome: ____________________ ____________________
Onset Date (dy/mth/yr) Resolved Date (dy/mth/yr)	Infection Type: ____________________ Primary Site: ____________________ Infectious Agent: ____________________	Treatments: ____________________ ____________________ Outcome: ____________________ ____________________
Onset Date (dy/mth/yr) Resolved Date (dy/mth/yr)	Infection Type: ____________________ Primary Site: ____________________ Infectious Agent: ____________________	Treatments: ____________________ ____________________ Outcome: ____________________ ____________________
Onset Date (dy/mth/yr) Resolved Date (dy/mth/yr)	Infection Type: ____________________ Primary Site: ____________________ Infectious Agent: ____________________	Treatments: ____________________ ____________________ Outcome: ____________________ ____________________
Onset Date (dy/mth/yr) Resolved Date (dy/mth/yr)	Infection Type: ____________________ Primary Site: ____________________ Infectious Agent: ____________________	Treatments: ____________________ ____________________ Outcome: ____________________ ____________________

Only if mandated by the protocol.

PHARMACOKINETICS

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:
Study Drug	Date of Dosing: (dy/mth/yr)	Clock Time Start Injection (hr:min):		Specimen Sampled*

Actual Time Point From Start of Injection (min)	Parent Drug Assay 1 /ml**	Parent Drug Assay 2 /ml**	Parent Drug Mean Conc. /ml**	Metabolite Assay 1 /ml**	Metabolite Assay 2 /ml**	Metabolite Mean Conc. /ml**

*Enter: B = Whole Blood; S = Serum; P = Plasma; C = CSF. If other, write in.

**Enter conc. units: (ug/ml), (ng/ml), (umoles/ml), other conventional abbreviation.

URINARY EXCRETION

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:	Sheet #:	Patient ID:
Date of Dosing: (dy/mth/yr)	Clock Time of Start of First Injection (hr:min):		Study Drug:	

Date (dy/mth/yr)	Time Start	Time Stop	Urine Volume ml	Parent Drug Assay 1 /ml*	Parent Drug Assay 2 /ml*	Parent Drug Mean Conc. /ml*	Parent Drug Amt in Void ( )**	Metabolite Assay 1 /ml*	Metabolite Assay 2 /ml*	Metabolite Mean Conc. /ml*	Metabolite Amt in Void ( )**

*Enter conc. units: (mg/ml), (ug/ml), (ng/ml), (moles/ml), or other conventional abbreviation.

**Enter units: mg. ug, moles, umoles, or other conventional abbreviation.

SCINTIGRAPHY

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:	Patient ID:
Trial #:		Date (dy/mth/yr):	

#1 Nuclide Name: _____	#2 Nuclide Name: _____
Aliquot count (ml): _____	Aliquot Count (ml): _____
#1 Antibody Name: _____	#2 Antibody Name: _____
Corrected/Aliquot CPM: _____	Corrected/Aliquot CPM: _____
Total Administered (ml): _____	Total Administered (ml): _____

Sample I.D. # / *Tissue Class	Source Organ / Description of Sample	Gamma Scan Positive** / CT Scan Positive**	Surgical Follow-Up *** Biopsied (Yes), Identified But Not Biopsied, Not Found	WT. of Sample (grams)	Percent Tumor	Corrected CPM of #1 Nuclide / #2 Nuclide
		Y / N / E	Y INB NF			
N / T		Y / N / E				
		Y / N / E	Y INB NF			
N / T		Y / N / E				
		Y / N / E	Y INB NF			
N / T		Y / N / E				
		Y / N / E	Y INB NF			
N / T		Y / N / E				
		Y / N / E	Y INB NF			
N / T		Y / N / E				

Circle the appropriate item in the asterisked columns.

*N = Normal; T = Tumor
**Y = Yes; N = No, E = Equivocal
***Y = Yes; INB = Identified but not biopsied; NF = Not found

PROTOCOL END POINT

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:
CDUS Patient Subgroup:	Treatment Assignment Code of the MTD:	

1	Dose Limiting Toxicity: _____ CDUS Toxicity Type Code: _____
2	Dose Limiting Toxicity: _____ CDUS Toxicity Type Code: _____
3	Dose Limiting Toxicity: _____ CDUS Toxicity Type Code: _____
4	Dose Limiting Toxicity: _____ CDUS Toxicity Type Code: _____
5	Dose Limiting Toxicity: _____ CDUS Toxicity Type Code: _____

FLOWSHEET A

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:	Sheet #:	Patient ID:

Lab Date (dy/mth/yr):							
Time (only if needed) hr : min		:	:	:	:	:	:
Notes:							
VITAL SIGNS (PL)	Performance Status						
	Height (cm)						
	Weight (kg)						
	Temperature (°C)						
	Pulse (/min)						
	Respiration Rate (/min)						
	Systolic BP (mmHG)						
	Diastolic BP (mmHG)						
TRANSFUSION	Whole Blood - Fresh (U)						
	Whole Blood Stored (U)						
	Packed Red Cells – Fresh (U)						
	Packed Red Cells - Stored (U)						
	Packed White Cells (U)						
	Platelets (U)						
CARDIAC	Pre-Ejection Period (PEP) (msec)						
	LV Ejection Time (msec)						
	LV Ejection Fraction (LVEF) (%)						
HEMATOLOGY (HM)	Hemoglobin (g/dl)						
	Hematocrit (%)						
	WBC (thousands/mm^3)						
	Bands (%)						
	Neutrophils (%)						
	Lymphocytes (%)						
	Basophils (%)						
	Monocytes (%)						
	Eosinophils (%)						
	Blast Cells (%)						
	Atypical Lymphs (%)						
	Other – Diff.						
	Platelets (thousands/mm^3)						
	ANC (thousands/uL)						
	RBC (thousands/mm^3)						
	Reticulocytes (%)						
	ESR (mm/hr)						
	PT (sec)						
	PTT (sec)						

FLOWSHEET B

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:	Sheet #:	Patient ID:

Lab Date (dy/mth/yr):								
Time (only if needed) hr : min		:	:	:	:	:	:	
Notes:								
BLOOD CHEMISTRIES (BC)	BUN	(mg/dl)						
	Creatinine	(mg/dl)						
	Sodium	(mEq/l)						
	Potassium	(mEq/l)						
	Chloride	(mEq/l)						
	Magnesium	(mg/dl)						
	Bicarbonate	(mEq/l)						
	Uric Acid	(mg/dl)						
	Bilirubin (total)	(mg/dl)						
	Alkaline Phosphate	(U/l)						
	SGOT (AST)	(U/l)						
	SGPT (ALT)	(U/l)						
	SGGT	(U/l)						
	LDH	(U/l)						
	Total Protein	(g/dl)						
	Albumin	(g/dl)						
	Globulin	(g/dl)						
	Calcium	(mg/dl)						
	Inorganic Phosphorus	(mg/dl)						
	Blood Glucose – Fasting	(mg/dl)						
	Blood Glucose – Non – Fasting	(mg/dl)						
	Cholesterol	(mg/dl)						
	Amylase	(U/l)						
	5’ Nucleotidase	(U/l)						
	Creatinine Phosphokinase (CPK)	(U/l)						
URINALYSIS (US)	Creatinine Clearance	(ml/min)						
	Acidity	(pH)						
	Specific Gravity							
	White Blood Cells	(0-4)						
	Red Blood Cells	(0-4)						
	Casts	(8 char)						
	Glucose	(mg/dl)						
	Protein	(mg/dl)						
	Ketones	(0-4)						
	Bile	(0-4)						
	Urinary Creatinine	(mg/dl)						
	Volume	(ml/24 hr)						
	Collection Period	(hr)						

FLOWSHEET C

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:	Sheet #:	Patient ID:

Lab Date (dy/mth/yr):								
Time (only if needed) hr : min		:	:	:	:	:	:	
BONE MARROW (BM)	Myeloblasts (%)							
	Promyelocytes (%)							
	Myelocytes: Neutros (%)							
	Eosinos (%)							
	Basos (%)							
	Metamyelocytes (%)							
	Polymorphs: Neutros (%)							
	Eosinos (%)							
	Basos (%)							
	Lymphocytes (%)							
	Plasma Cells (%)							
	Monocytes (%)							
	Reticulum Cells (%)							
	Megakaryocytes (%)							
	Pronormoblasts (%)							
	Normoblasts (%)							
	Cellularity (8 char)							
	M Rating (1-7)							
Serology (SR)	PSA							
	CA125							
	CEA							
	CA19-9							
	CA15-3							
	CA27, 29							
	AFP							
	HCG (+,-)							
	HIV (+,-)							
	HbsAg (+,-)							
	Pregnancy (+,-)							
	Stool Guaiac (+,-)							
Other Serum Chemictries (SC)	Aldolase (U/l)							
	Ammonia (μmol/l)							
	Calcium – Ionized (mg/dl)							
	Copper (μg/dl)							
	Ferritin (μg/dl)							
	HDL (μg/dl)							
	Insulin (μU/ml)							
	Iron (μg/dl)							
	Iron Binding Capacity (μg/dl)							
	Iron Saturation (%)							
	LDL (mg/dl)							
	Lipase (U/l)							
	Osmolality (m)sm/kg)							
	Acid Phosphatase (U/l)							
	Transferrin (mg/dl)							
	Triglycerides (mg/dl)							
	T3							
	T4							
	TSH							

FLOWSHEET D

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr) :	Protocol #:	Institution:	Sheet #:	Patient ID:

Lab Date (dy/mth/yr):								
Time (only if needed) hr : min		:	:	:	:	:	:	
Notes:								
BLOOD GASES (RF) RESPIRATORY FUNC.	pH	(pH)						
	pCO_2	(mmHg)						
	pO_2	(mmHg)						
	Bicarbonate	(mEq/l)						
	Base Excess	(mmol/l						
	Base Deficit	(mmol/l)						
	Oxygen Saturation	(%)						
	CO	(%)						
	Methemoglobin	(% total hgb)						
	Vital Capacity	(l)						
	Expiratory Volume (FEV1)	(%/sec)						
	Maximum Capacity	(l)						
	Residual Volume	(l)						
	Tidal Volume	(l)						
	Functional Residual Capacity	(l)						
	Pulmonary Compliance	(dV/dP)						
	Diffusing Capacity (DLCO)	(l/sec)						
	Maximum EXP. FLOW	(l/sec)						
	Maximum Mid – Exp Flow	(l/sec)						
RED CELL INDICES (RC)	MCH	(pg)						
	MCHC	(%)						
	MCV	(fl)						
	Bleeding Time	(min)						
	Clot Retraction Screen	(hr)						
	Semi Quant	(%)						
	Quantitive							
	Clotting Time	(min)						
	FDP	(µg/ml)						
	Fibrinogen	(mg/dl)						
	Thrombin Time	(sec)						
	Nucleated RBCs	(%)						
	Complement	(U/ml)						
	Coombs Test	(pos/neg)						
	Antinuclear Factor (ANF)	(ratio)						
OTHER URINARY RESULTS (OU)	Calcium	(mg/24 hr)						
	Chloride	(mg/24 hr)						
	Osmolality	(m0sm/kg)						
	Oxalate	(mg/24 hr)						
	Potassium	(mEq/24 hr)						
	Protein – Albumin	(g/dl)						
	ALPHA 1	(%)						
	ALPHA 2	(%)						
	BETA	(%)						
	GAMMA	(%)						
	Sodium	(mEq/24 hr)						
	Urea Nitrogen	(g/24 hr)						
	Uric Acid	(mg/24 hr)						

FLOWSHEET E

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:	Sheet #:	Patient ID:

Lab Date (dy/mth/yr):							
Time (only if needed) hr : min		:	:	:	:	:	:
Notes:							
IMMUNE PARAMETERS (IP)	Lymphocyte Blasts						
	B – Cell Level						
	T – Cell Total						
	Helper						
	Suppressor						
	DTH						
	CTL						
	NK Activity						
	ADCC						
	Macrophage Cytotoxicity						
	Macrophage Cytostasis						
	Peroxide Generation						
	Serum Interferon						
SERUM ELECTRO. (SE)	Ig A (mg/dl)						
	Ig D (mg/dl)						
	Ig E (mg/dl)						
	Ig G (mg/dl)						
	Ig M (mg/dl)						
	Monoclonal (0 or #)						
	Polyclonal (0 or #)						
	Kappa (0 or #)						
	Lambda (0 or #)						
	Bence – Jones (0 or #)						
URINE IMMUNE ELECTRO. (UE)	Ig A (mg/dl)						
	Ig D (mg/dl)						
	Ig E (mg/dl)						
	Ig G (mg/dl)						
	Ig M (mg/dl)						
	Monoclonal (0 or #)						
	Polyclonal (0 or #)						
	Kappa (0 or #)						
	Lambda (0 or #)						
	Bence – Jones (0 or #)						
ELECRRO. (RC)	Total Serum Protein (g)						
	Albumin (%)						
	ALPHA 1 (%)						
	ALPHA 2 (%)						
	Beta (%)						
	Gamma (%)						

FLOWSHEET F

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:	Sheet #:	Patient ID:

	Date (dy/mth/yr) / Time (hr:min)	Test Name* (See below)	Body Site** / Normal/Abnormal	Result
1.	_____ :		_____ N / A	
2.	_____ :		_____ N / A	
3.	_____ :		_____ N / A	
4.	_____ :		_____ N / A	
5..	_____ :		_____ N / A	
6.	_____ :		_____ N / A	
7.	_____ :		_____ N / A	
8.	_____ :		_____ N / A	

*Use this form only for the following tests:

CEKG	Electrocardiogram	EEG	Electroencephalogram
CXR	Chest x-ray	BMCELLTY	BM Cellularity
BRNCHGRM	Bronchogram	UCASTS	Urine Casts
UPGISER	Upper GI Series	MUGASCAN	Muga Scan
LOGISER	Lower GI Series	ULTRASND	Ultra Sound
SKELSURV	Skeletal Survey	CATSCAN	Cat Scan
HOLTMON	Holter Monitor	MRI	MRI
BONESCAN	Bone Scan	XRAY	x-ray

**For CAT Scan and MRI please use the following body sites where applicable: Thorax, Abdomen, Pelvis, Brain.

SPECIAL NUMERIC LABS

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed : (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

PANEL #	DATE	__/__/__ dy/mth/yr	__/__/__ dy/mth/yr	__/__/__ dy/mth/yr	__/__/__ dy/mth/yr	__/__/__ dy/mth/yr	__/__/__ dy/mth/yr
ASSIGNED TEST	TIME (if needed)	:	:	:	:	:	:
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
11.							
12.							
13.							
14.							
15.							
16.							
17.							
18.							
19.							
20.							
21.							
22.							
23.							
24.							
25.							

*This form is to be used only for specific lab test names assigned by CTMS for this protocol.

SPECIAL LITERAL LABS

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed	Protocol	Institution	Sheet #	Patient ID

PANEL # ASSIGNED TEST NAME*		DATE (dy/mth/yr)	TIME (hr:mn)	RESULT
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

*This form is to be used only for specific lab test names assigned by CTMS for this protocol.

UNANTICIPATED LAB DATA

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:	Sheet #:	Patient ID:

Date (dy/mth/yr) / Time (hr:min)	Lab Test	Body Site	Normal/Abnormal / Result Type Numeric/Lateral	Result
_____ :			N / A N / L	
_____ :			N / A N / L	
_____ :			N / A N / L	
_____ :			N / A N / L	
_____ :			N / A N / L	
_____ :			N / A N / L	
_____ :			N / A N / L	
_____ :			N / A N / L	
_____ :			N / A N / L	
_____ :			N / A N / L	